



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-P-0948]

Determination That STAVZOR (Valproic Acid) Delayed-Release Capsules, 125 Milligrams, 250 Milligrams, and 500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined that STAVZOR (valproic acid) delayed-release capsules, 125 milligrams (mg), 250 mg, and 500 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for valproic acid, delayed-release capsules, 125 mg, 250 mg, and 500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Na'im R. Moses, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6223, Silver Spring, MD 20993-0002, 240-402-3990.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products under an ANDA procedure.

ANDA applicants must, with certain exceptions, show that the drug for which they are seeking

approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA).

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162).

A person may petition the Agency to determine, or the Agency may determine on its own initiative, whether a listed drug was withdrawn from sale for reasons of safety or effectiveness. This determination may be made at any time after the drug has been withdrawn from sale, but must be made prior to approving an ANDA that refers to the listed drug (§ 314.161 (21 CFR 314.161)). FDA may not approve an ANDA that does not refer to a listed drug.

STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, is the subject of NDA 22-152, held by Banner Pharmacaps Inc., and initially approved on July 29, 2008. STAVZOR is indicated for acute treatment of manic or mixed episodes associated with bipolar disorder (with or without psychotic features), monotherapy and adjunctive therapy of complex partial seizures and simple and complex absence seizures, adjunctive therapy in patients

with multiple seizure types that include absence seizures, and prophylaxis of migraine headaches.

In a letter dated June 25, 2013, Banner Pharmacaps Inc. notified FDA that STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, was being discontinued, and FDA moved the drug product to the "Discontinued Drug Product List" section of the Orange Book.

Pharmaceutics International, Inc., submitted a citizen petition dated August 7, 2013 (Docket No. FDA-2013-P-0948), under 21 CFR 10.30, requesting that the Agency determine whether STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records and based on the information we have at this time, FDA has determined under § 314.161 that STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events. We have reviewed the available evidence and determined that product was not withdrawn from sale for reasons of safety or effectiveness.

Accordingly, the Agency will continue to list STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to STAVZOR (valproic acid) delayed-release capsules, 125 mg, 250 mg, and 500 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: February 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.